

K 963573

Beiersdorf-Jobst, Inc.

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510(k) Summary of Safety and Effectiveness

This submission covers Elvarex compression garments which are classified as medical support stockings (21 CFR §880.5780). The Elvarex garments are equivalent to the preamendment Jobst-Custom garments which are used for the same indications.

While Jobst-Custom garments are cut and sewn from fabric made of spandex and nylon yarns, the Elvarex garments are flat knit using yarns made of nylon, natural rubber latex, cotton and spandex and then sewn together.

Both products use the specific measurements for a patient and calculate the final garment dimensions using the LaPlace formula. Compression is provided for both products by large elastic yarns that act circumferentially on the limb. The gradient compression present with both products helps to force fluid into the deep venous system and in the return of lymphatic fluid. Consequently, they can be used to treat the same indications, i.e. CVI, edema, lymphedema, phlebitis and vascular malformations. The contraindications for the two products are also the same, i.e. significant arterial insufficiency, cutaneous infections, dermatitis in the acute phase, wet dermatosis and conditions in which venous and lymphatic return is not desired.

Elvarex has been on the market for several years in Europe and has an established track record. There have also been no reports of serious injury resulting from its use during the three year period assessed.

The product being submitted is substantially equivalent to the predicate product in the materials used, mode of action, and indications of use. It also has a long history of use and has proven to be as safe and effective as the predicate product.

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